K063262

**EXHIBIT 2**
**510(k) Summary**


DEC 2 6 2006

**720 S. Powerline Road Suite E**
**Deerfield Beach, FL 33442**
**954-428-6191 (Office)**
**954-428-6195 (Fax)**
**October 18, 2006**
**Contact: Chris Duca, COO**

1. **Identification of the Device:**
   **Proprietary-Trade Name:** AMX4-50 and AMX4-31 Mobile Digital Diagnostic Radiographic Systems (Also offered as an upgrade kit to owners of the GE AMX-4 Plus Mobile X-Ray System: AMX4—50 Retrofit Kit)
   **Classification Name:** System, x-ray, mobile
   **Product Code** Product Code IZL
   **Common/Usual Name:** Mobile X-Ray System

2. **Equivalent legally marketed device:** GE AMX-4 Plus Mobile X-ray System, K021016 and CANON CXDI-50G Digital Radiography, K031447. The remanufactured device COMBINES these two units with an integrated control. A similar unit in the market would be the Sedecal Mobile X-Ray Units with Digital Detector, K043002.

3. **Indications for Use (intended use)** Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. **Description of the Device:** The AMX4-50 is an AMX portable that has been upgraded to accommodate the Canon 50G digital imaging system. The AMX4 will operate in the same manner as before except that, instead of using film cassettes, it will be making digital images with the Canon sensor. The original AMX system is disassembled and reconstructed with new batteries, a DC to AC power supply for the Canon digital imaging system, and enclosure sheet metal to accommodate the modifications. An added control coordinates x-ray exposure and digital image acquisition. The AMX4-50 uses the Canon CXDI-50G and the AMX4-31 uses the Canon CXDI-31 portable detector.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

## 6. Substantial Equivalence Chart, "AMX4-50 and AM[redacted]

| Characteristic | GE AMX-4 Plus Mobile X-ray System, K021016 | Sedecal Mobile X-Ray Units with Digital Detector, K043002. | [redacted]X4-50 and [redacted]X4-31 Mobile [redacted] Diagnostic [redacted]diographic Systems and AMX4—50 Retrofit Kit |
|---|---|---|---|
| Intended Use: | Mobile diagnostic x-ray | SAME | SAME |
| Power source | Batteries charged by AC line | SAME | SAME |
| Image acquisition | X-ray film | Canon Digital P[redacted] CXDI-50G | [redacted]gital Panel CXDI-50G or the CXDI-31 portable detector (K003689/ K023750) |
| User Interface | [redacted] | Software Driven Touch Panel LCD | Software Driven Touch Panel LCD for Digital Panel, Generator controls are NOT modified |
| Digital Resolution | N/A | 160 x 160 microns pixel pitch, with approximately 6 million pixels and 4,096 gray scale contrast | SAME (Combined device) or 100 x 100 microns for AMX4-31 with 6.5 million pixels. 4,096 gray scale contrast |
| Available panel sizes | N/A | CXDI-50G<br>35 x 43 cm | CXDI-50G<br>35 x 43 cm<br>CXDI-31<br>22.6 x 28.8cm |
| Performance Standard | Complies with 21 CFR Part 1020 | SAME | SAME |
| Electrical safety | UL/IEC | SAME | SAME |

## 7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Virtual Imaging that the AMX4-50 and AMX4-31 System is as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Virtual Imaging, Inc.
% Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

DEC 26 2006

Re: K063262
Trade/Device Name: AMX4-50 and AMX4-31 Mobile Digital Diagnostic Radiographic System (Also offered as an upgrade kit to owners of the GE AMX-4 Plus Mobile X-Ray System: AMX4-50 Retrofit Kit)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: October 26, 2006
Received: October 31, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K063262

Device Name: AMX4-50 and AMX4-31 Mobile Digital Diagnostic Radiographic Systems (Also offered as an upgrade kit to owners of the GE AMX-4 Plus Mobile X-Ray System: AMX4—50 Retrofit Kit)

Indications For Use:

Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063262